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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,369	01/12/2005	Larry L. Berger	CL2178USPCT	2257

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EXAMINER	
RAZA, SAIRA B	
ART UNIT	**PAPER NUMBER**
1711	

DATE MAILED: 04/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/521,369	BERGER ET AL.	
	Examiner	Art Unit	
	Saira Raza	1711	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-29 is/are pending in the application.

4a) Of the above claim(s) 12-14 and 21-29 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) 1-11 and 15-20 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 8/25/2005.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Claims 12-14 and 21-28 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 6 March 2006.

2. Applicant's species election with traverse of ibuprofen, Eudragit ® L30D, and silica in the reply filed on 6 March 2006 is acknowledged. The traversal is on the ground(s) that the patentability of the claimed processes does not rely on the specific composition of the coating material. This is not found persuasive because applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. MPEP § 809.02(a).

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 3, 8, and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. A trademark is used in the claims as a limitation to identify or describe a particular material or product; hence the claims do not comply with the requirements of the 35 U.S.C. 112, second paragraph. *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain

since the trademark or trade name cannot be used properly to identify any particular material or product. In fact, the value of a trademark would be lost to the extent that it became descriptive of a product, rather than used as an identification of a source or origin of a product. Thus, the use of a trademark or trade name in a claim to identify or describe a material or product would not only render a claim indefinite, but would also constitute an improper use of the trademark or trade name.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Schurr (WO 97/07879). (See Schurr at Page: Lines :: Abstract, 2:12-39, 5:3-17, 9:3-16).

6. Schurr discloses a process for coating a particle with a liquid, the process comprising the steps of:

a) metering a liquid composition (comprising a coating material) into a flow restrictor;

b) injecting a heated gas stream through the flow restrictor concurrently with the metering of the liquid composition to create a zone of turbulence and thereby atomizing the liquid composition;

c) adding a solid particle to the zone of turbulence concurrently with the metering of the liquid composition and injection of the heated gas to mix the solid particle with the atomized liquid composition; the mixing at the zone of turbulence coats the solid particle with the coating material.

7. Schurr states the process is suitable for coating solid particles and in particular, small particles, such as powdery or granular materials. Hence, Schurr would envisage coating small pharmaceutical particles via the process disclosed above.

8. In reference to claim 4, Schurr discloses that steps (a) to (c) can be repeated more than once with the same liquid composition.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 1, 2, 3, 4, 7, 8, 9, 15, 16, 17, 18, 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Amey (US 5,800,923) in view of Mehta (US 4,800,087). (See Amey at Column: Lines :: 4:24-29, 5:43-48, and claim 14; See Mehta at Column: Lines :: Abstract, 3:40-43, 4:24-62, 5:6-20, 7:31-48, 8:13 to 9:18, Claim 11).

12. In reference to claim 1, Amey discloses a process for coating a particle with a liquid, the process comprising the steps of:

a) metering a liquid composition (comprising a coating material) into a flow restrictor;

b) injecting a heated gas stream through the flow restrictor concurrently with the metering of the liquid composition to create a zone of turbulence and thereby atomizing the liquid composition;

c) adding a solid particle to the zone of turbulence concurrently with the metering of the liquid composition and injection of the heated gas to mix the solid particle with the atomized liquid composition; the mixing at the zone of turbulence coats the solid particle with the coating material.

13. Amey states the process is suitable for coating carboxylic acid solid particles and in particular, small particles, such as powdery or granular materials. Amey does not expressly disclose that pharmaceutical particles can be utilized as the solid particles. Hence attention is directed towards the Mehta reference. Amey and Mehta are analogous art because they are from the same field of endeavor, formation of microencapsulated products. Mehta discloses microcapsules comprised of a core of a pharmaceutical particle (such as a anti-inflammatory drug, ibuprofen), and a shell or coating of a biodegradable polymer (such as Eudragit ® RL30D). At the time of the invention, it would have been obvious to a person of ordinary skill in the art to substitute a pharmaceutical particle for the carboxylic acid particle in the process of Amey in order to obtain encapsulated ibuprofen which would eliminate the bitter taste; hence, make the drug more pleasant to take orally. At the time of the invention one of ordinary skill in the art would have considered it "logical to anticipated with a high degree of probability that a trial of the substitution of would have been successful." *In re Pantzer,* 341 F2d. 121, 126;144 USPQ 415, 419 (CCPA 1965). Only a reasonable expectation of success, not absolute predictability is necessary for obviousness. *In re Longi,* 759F.2d 887, 897, 225 USPQ 645, 651-52 (Fed. Cir. 1985). In reference to claim 4, Amey discloses that the process can be repeated more than once with the same liquid composition. It

would have been obvious to one of ordinary skill in the art at the time of the invention to repeat the process of claim 1 more than once in order to adhere additional coating material to the solid particle.

14. In reference to claim 6, the combination of Amey and Mehta applies as above. The combination of Amey and Mehta fail to teach that instead of adding the pharmaceutical particles in step (c), the particles are included in the coating liquid of step (a); however this modification is recognized as changes in sequence of adding ingredients. It has been held that the selection of any order of mixing ingredients is prima facie obvious; *In re Gibson*, 39 F.2d 975, 5 USPQ 230 (CCPA 1930); *In re Burhans*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946); *Ex parte Rubin*, 128 USPQ 440 (Bd. App. 1959). In reference to claim 9, the process can be repeated more than once with the same liquid composition. It would have been obvious to one of ordinary skill in the art at the time of the invention to repeat the process of claim 6 more than once in order to adhere additional coating material to the solid particle.

15. In reference to claims 16, 17, 18 and 20 the combination of Amey and Mehta applies as applies as above to claims 1 and 6. The combination fails to teach that a coating liquid comprising a carrier particle is metered into the flow restrictor, and that the solid pharmaceutical particle can be an anti-inflammatory particle. Hence attention is directed towards the Mehta reference. Mehta discloses microcapsules comprised of a core of an anti-inflammatory drug (such as ibuprofen), and a shell or coating of a biodegradable polymer (such as Eudragit ® RL30D). Mehta discloses in the process of formation of the microcapsule, the coating liquid comprises a biodegradable polymer in addition to a pigment, such as titanium dioxide. Wherein applicant recognizes in claims 17 and 18 that titanium dioxide is an inert material which functions as a carrier particle. Mehta discloses that the core pharmaceutical product should be in granular form prior to encapsulation. At the time of the invention, it would have been obvious to a person of ordinary skill in the art to include carrier

particles in the coating liquid, and to utilize ibuprofen (an anti-inflammatory) granules as the solid pharmaceutical particle in the process of Amey in order to obtain encapsulated ibuprofen. The suggestion/motivation to include carrier particles, such as titanium dioxide would have been obvious in order to stabilize and enhance the shelf life of the pharmaceutical core material, which may be light sensitive or unstable. The suggestion/motivation to utilize ibuprofen granules would have been obvious in order to eliminate the bitter taste; hence, make the drug more pleasant to take orally. Wherein it is inherent that upon addition of the coating liquid comprising the pharmaceutical product and the carrier particles, the carrier particles will mix with the atomized coating liquid in the region of turbulent flow to provide a particle coated with a pharmaceutically active ingredient.

16. The above combination of Amey and Mehta fails to teach that instead of the carrier particles being present in the coating liquid, the carrier particles can be separately added, as in claim 15. However this modification is recognized as changes in sequence of adding ingredients. It has been held that the selection of any order of mixing ingredients is prima facie obvious; *In re Gibson*, 39 F.2d 975, 5 USPQ 230 (CCPA 1930); *In re Burhans*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946); *Ex parte Rubin,* 128 USPQ 440 (Bd. App. 1959).

17. In reference to claims 2, 3, 7, and 8 Amey fails to teach that the solid pharmaceutical particle can be an anti-inflammatory particle coated with a biodegradable polymer. Hence attention is directed to the Mehta reference whose disclosure is provided above. At the time of the invention, it would have been obvious to a person of ordinary skill in the art to utilize ibuprofen granules as the solid pharmaceutical particle, and utilize a biodegradable polymer (such as Eudragit ® RL30D) as the coating liquid in the process of Amey in order to obtain encapsulated ibuprofen. The suggestion/motivation to utilize ibuprofen granules would have been obvious in order to eliminate the bitter taste; hence, make the drug more pleasant to take orally. The suggestion/motivation to

utilize a biodegradable polymer (such as Eudragit ® RL30D) as the coating material would have obvious in order to ensure the active agent is released in the stomach after chewing.

18. Claims 2, 3, 6, 7, 8, 9, 15, 16, 17, 18, 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schurr (WO 97/07879) in view of Mehta (US 4,800,087).

19. In reference to claims 6 and 9, The Schurr reference applies as above. The Schurr reference fails to disclose or teach that instead of adding the pharmaceutical particles in step (c), the particles are included in the coating liquid of step (a); however this modification is recognized as changes in sequence of adding ingredients. It has been held that the selection of any order of mixing ingredients is prima facie obvious; *In re Gibson*, 39 F.2d 975, 5 USPQ 230 (CCPA 1930); *In re Burhans*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946); *Ex parte Rubin*, 128 USPQ 440 (Bd. App. 1959). In reference to claim 9, that the process can be repeated more than once with the same liquid composition. It would have been obvious to one of ordinary skill in the art at the time of the invention to repeat the process of claim 6 more than once in order to adhere additional coating material to the solid particle.

20. In reference to claims 16, 17, 18 and 20 the Schurr reference applies as above to claims 1 and 6 above. Schurr fails to expressly disclose that a coating liquid comprising a carrier particle is metered into the flow restrictor, and Schurr fails to expressly disclose that the solid pharmaceutical particle can be an anti-inflammatory particle. Hence attention is directed towards the Mehta reference. Schurr and Mehta are analogous art because they are from the same field of endeavor, formation of microencapsulated products. Mehta discloses microcapsules comprised of a core of an anti-inflammatory drug (such as ibuprofen), and a shell or coating of a biodegradable polymer (such as Eudragit ® RL30D). Mehta discloses in the process of formation of the microcapsule, the coating liquid comprises a biodegradable polymer in addition to a pigment, such as titanium dioxide. Wherein applicant recognizes in claims 17 and 18 that titanium dioxide is an inert material which

functions as a carrier particle. Mehta discloses that the core pharmaceutical product should be in granular form prior to encapsulation. At the time of the invention, it would have been obvious to a person of ordinary skill in the art to include carrier particles in the coating liquid, and to utilize ibuprofen (an anti-inflammatory) granules as the solid pharmaceutical particle in the process of Schurr in order to obtain encapsulated ibuprofen. The suggestion/motivation to include carrier particles, such as titanium dioxide would have been obvious in order to stabilize and enhance the shelf life of the pharmaceutical core material, which may be light sensitive or unstable. The suggestion/motivation to utilize ibuprofen granules would have been obvious in order to eliminate the bitter taste; hence, make the drug more pleasant to take orally. Wherein it is inherent that upon addition of the coating liquid comprising the pharmaceutical product and the carrier particles, the carrier particles will mix with the atomized coating liquid in the region of turbulent flow to provide a particle coated with a pharmaceutically active ingredient.

21. The above combination of Schurr and Mehta fails to teach that instead of the carrier particles being present in the coating liquid, the carrier particles can be separately added, as in claim 15. However this modification is recognized as changes in sequence of adding ingredients. It has been held that the selection of any order of mixing ingredients is prima facie obvious; *In re Gibson*, 39 F.2d 975, 5 USPQ 230 (CCPA 1930); *In re Burhans*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946); *Ex parte Rubin*, 128 USPQ 440 (Bd. App. 1959).

22. In reference to claims 2, 3, 7, and 8 Schurr fails to expressly disclose that the solid pharmaceutical particle can be an anti-inflammatory coated with a biodegradable polymer. Hence attention is directed towards the Mehta reference, whose disclosure is provided above. At the time of the invention, it would have been obvious to a person of ordinary skill in the art to utilize ibuprofen granules as the solid pharmaceutical particle, and utilize a biodegradable polymer (such as

Eudragit ® RL30D) as the coating liquid in the process of Schurr in order to obtain encapsulated ibuprofen. The suggestion/motivation to utilize ibuprofen granules would have been obvious in order to eliminate the bitter taste; hence, make the drug more pleasant to take orally. The suggestion/motivation to utilize a biodegradable polymer (such as Eudragit ® RL30D) as the coating material would have obvious in order to ensure the active agent is released in the stomach after chewing.

23. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Amey and Mehta and unpatentable over the combination of Schurr and Mehta as applied to the claims above, and further in view of Cohrs et al. (US 4,016,110).

24. The combinations of Amey and Mehta and of Schurr and Mehta fail to disclose that the carrier particle is silica. Hence attention is directed towards the Cohrs reference (1:38-57). Amey, Mehta, Schurr, and Cohrs are analogous art because they are from the same field of endeavor, formation of microcapsules. Cohrs discloses that silica can be employed as a dispersing agent. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to have utilized silica as a carrier particle in the combined process (as taught by both Amey and Mehta and Schurr and Mehta) in order to ensure that the particles remain dispersed.

Claim Rejections - 35 USC § 102 / 103

25. Claims 5, 10, 11 and 19 are recognized as product-by-process claims, even though product-by-process claims are limited by and defined by the process; determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

26. Claims 5, 10, 11, and 19 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Mehta (US 4,800,087).

27. Mehta discloses a coated pharmaceutical particle. Mehta discloses microcapsules comprised of a core of an anti-inflammatory drug (such as ibuprofen granules), and a shell or coating of a biodegradable polymer (such as Eudragit ® RL30D). The process of forming the coated particle comprises utilizing fluid bed equipment, which makes use of a Wurster insert (bottom spray mode), a conventional granulating insert (top spray mode), or a rotary granulator (tangential spray mode). The pharmaceutical particle/granule and the biodegradable polymer coating liquid are the starting materials in the process. Mehta discloses that the coating liquid can contain pigments, such as titanium dioxide, which can function as the claimed carrier particles. The claimed products appear to be the same or similar to that of the prior art, although produced by a different process. The examiner has provided a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. *In re Marosi,* 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983).

Double Patenting

28. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg,* 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman,* 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi,* 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum,* 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel,* 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

29. Claims 1-20 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 14-17 of U.S. Patent No. 5,800,923 (Amey) in view of Mehta (US 4,800,087). Amey claims a process for coating a carboxylic acid solid particle and the herein application claims a process for coating a pharmaceutical particle. In view of the Mehta reference, as applied above, it would have been obvious to one of ordinary skill at the time of the invention to have substituted a pharmaceutical particle for the carboxylic acid solid particle in the process of Amey in order to obtain the invention as claimed herein. At the time of the invention one of ordinary skill in the art would have considered it "logical to anticipated with a high degree of probability that a trial of the substitution of would have been successful." *In re Pantzer,* 341 F2d. 121, 126;144 USPQ 415, 419 (CCPA 1965).

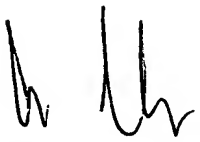
30. Claims 1-20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 of copending Application No. 10/174,687 in view of Mehta. The copending application claims a process for coating a food particle and the herein application claims a process for coating a pharmaceutical particle. In view of the Mehta reference, as applied above, it would have been obvious to one of ordinary skill at the time of the invention to have substituted a pharmaceutical particle for the food particle in the copending application to obtain the invention as claimed herein.

This is a provisional obviousness-type double patenting rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Saira Raza whose telephone number is (571) 272-3553. The examiner can normally be reached on Monday-Friday from 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on (571) 272-1078. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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